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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,162	09/18/2003	Jinhu Xiong	ACC.0002US	7082
21906 7590 07/09/2008 TROP PRUNER & HU, PC 1616 S. VOSS ROAD, SUITE 750 HOUSTON, TX 77057-2631				
EXAMINER LAMPRECHT, JOEL				
ART UNIT 3737		PAPER NUMBER		
NOTIFICATION DATE 07/09/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary

Application No.

10/666,162

Applicant(s)

XIONG ET AL.

Examiner

JOEL M. LAMPRECHT

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-21, 23, 25-32, 34-38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-21, 23, 25-32, 34-38 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 38 is objected to because of the following informalities: Claim 38 appears to contradict claim 14 which recites that hemodynamic activity is not measured. In order to perform the method of claim 38, at least some measurement of hemodynamic changes would be required to enable one to time the mapping of electromagnetic activity during a time window related to hemodynamic change. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-21, 23, 25-32, 34-38, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. With regard to the independent claims of record, it is noted that they all comprise at least language stating that direct detection of regional neural activity is performed without measurement of hemodynamic or metabolic changes.

Specifically regarding claim 1 it is stated that regional neural activity is measured without measurement of hemodynamic or metabolic changes as a result of regional

neural activity and occurs in a time window prior to hemodynamic activity in the subject as a result of regional neural activity. As understood by Examiner, Applicant's specification provides that hemodynamic activity is monitored so as to acquire regional neural activity at a time period where the hemodynamic response is maintained at a plateau of activity based from a response to a series of stimuli, requiring monitoring or measurement of some sort, of the hemodynamic response of a patient. Additionally, hemodynamic activity and regional neural activity are constantly occurring processes in living organisms and the description of the "time window prior to hemodynamic activity as a result of the regional neural activity" should be further defined to recite that specific regional neural responses *to a specific stimulus* are measured before the corresponding hemodynamic response takes place as a baseline level of regional neural activity and hemodynamic responses are constantly occurring within the brain and the methods provided by the specification use a number of previous $T < T_0$ stimuli to "ramp up" or "plateau" the hemodynamic response for measurement of regional neural activity.

With regard to independent claim 14, similar language exists to that of claim 1; specifically that direct mapping of regional neural activity is performed without measurement of hemodynamic or metabolic changes.

With regard to claim 23, again the regional neural activity is measured at least in part based on some sort of measurement or knowledge of the hemodynamic response provided by a series of stimuli, and the regional neural activity is the result of some stimulus which is measured before the corresponding hemodynamic response takes place.

Regarding claim 26, again the measurement is at least based in part on the measurement or knowledge of the hemodynamic response to a series of fast stimuli in order to effect a preferred environment for measurement of regional neural activity within the subject.

Regarding claim 34, similar wording exists as that discussed above, including "prior to hemodynamic changes of the subject as a result of neuronal activity of the subject", which differs from Applicant's specification because regional neuronal activity is measured in a window prior to the hemodynamic response to a specific stimulus in a series of stimuli which are administered and the hemodynamic response is measured or accounted for through such a series of fast stimuli administered to the patient.

Finally, Applicant's invention as provided within the specification recites that "hemodynamically neutral" as relates to embodiments of Applicant's application means obtaining of data during time periods where hemodynamic effects are substantially steady state. In order to maintain a steady state hemodynamic response, a series of "fast" stimulations are administered to the patient to maintain hemodynamic responses at a high level or plateau. While it is acknowledged that repeated attempts of Applicant's procedure would train one skilled in the art to acquire knowledge of precise times of stimuli which would maintain the hemodynamic response at a high level, it still follows that it is the maintenance of these hemodynamic responses at such a high level that provides the time window for acquisition (Application, paragraphs 40 and 42). This hemodynamic response is acknowledged as not being the "goal" *per se* of Applicant's invention, but never-the-less does provide the window for data acquisition and the

relationship between the hemodynamic response and the acquisition of data should thereby be recited to allow for one of ordinary skill in the art to be able to perform Applicant's procedure and/or use Applicant's invention.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 9-21, 23, 25-32, 34-38, and 41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure has been cited on the corresponding Notice of References Cited form. Included are background patents by John A Cadwell, Davey et al, and Dossel et al, which related to measurement of electrical or other magnetic responses created by the brain, as well as a patent by Robinson (6,697,660) relating MEG measurements to providing functional 3d images of the brain. The references to Ives et al and Robinson et al show further implementations of localized neural stimulation and imaging, and the reference provided by Fox et al is to at least one of the same inventors of the instant application and provides further information for the understanding of how methods of other modalities are incorporated into the procedures set forth by Applicants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is

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(571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JML